UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/559,021	04/27/00	SOKOLOFF	A	MIRUS.014.02

HM12/1219

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EXAMINER	
LEFFERS JR, G	
ART UNIT	**PAPER NUMBER**
1636	6

DATE MAILED: 12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/559,021	Wolff, et al.
Examiner	**Group Art Unit**
Gerald G. Leffers Jr.	1636

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-16* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Receipt is acknowledged of applicants' preliminary amendment, filed 11/15/00, in which new claims 2-16 were added.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no CRF was filed, no paper sequence was filed and no attorney statement was filed. These sequences include, for example, the primer sequences listed throughout the specification (e.g. primer sequences on page 36) and the amino acid sequences listed throughout the specification (e.g. Figure 1, Table 1, page 30, etc.). If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. *Any* response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Priority

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph, rather than in a Table format as is done in the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Pasqualini et al (AS; see the entire reference).

Pasqualini et al teach methods of organ targeting in vivo utilizing phage display peptide libraries which display peptides that direct the phage to particular target organs (Abstract). In the methods taught by Pasqualini et al, phage bearing randomly displayed peptide sequences capable of directing phage to brain tissue were selected following injection of the phage into the tail vein of rats. Phage recovered from the brains of injected animals were amplified in bacteria and re-

injected in multiple rounds of selection (Figure 1). As the recovered phage were not inactivated following rejection, they must comprise peptide sequences which prevent phage inactivation (e.g. capsid proteins, etc.).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that there is no indication in the claim preamble as to what the claimed process in intended to accomplish. Claim 1 is also vague and indefinite in that the metes and bounds of the term "useful epitopes" are unclear. The term is inherently subjective in the absence of an indication of what the claimed method is to accomplish. It would be remedial to amend the claim language to clearly indicate in the preamble what the claimed method is to accomplish and what exactly constitutes a "useful" epitope.

Claim 2 is vague and indefinite in that it is grammatically incorrect to specify a "..process for selecting phage that is resistant..". It is likewise grammatically incorrect to specify "..mixing a blood component with a phage display; selecting a phage..." (examiner's emphasis added).

Upon reading the specification, it appears applicants intend to specify a process for selecting phage that are resistant to blood inactivation which comprises mixing a blood component with a phage display library and selecting for phage which are resistant to inactivation by the blood component.

Claim 3 is vague and indefinite in that the metes and bounds of the phrase "..wherein the phage display comprises multiple rounds of selection." are unclear. The phrase is unclear in that it appears to specify that a composition comprises multiple methods steps. It appears that the phrase may be intended to specify that the step of selection comprises multiple rounds of selection.

Claim 4 is vague and indefinite in that it is improper to say that a phage "consists of" a species of phage. It would be remedial to amend the claim to read something like "..wherein the phage display library comprises T7 phage..".

Claim 8 is vague and indefinite in that the metes and bounds of the phrase "..a peptide that prevents inactivation." are unclear. It is unclear as the claim is written as to what would constitute a peptide that prevents phage inactivation. Read in one sense, the phrase encompasses any structural polypeptide (e.g. capsid proteins) which protect the phage from the environment. Upon reading the specification, it appears that the phrase is meant to refer to phage inactivation by blood components. It would be remedial to amend the claim language to clearly indicate what is meant by the phrase "a peptide that prevents inactivation. Also, claim 8 is grammatically

incorrect in that there is no requirement for the colon following the word "comprising" since there is only one element following "comprising".

Claim 9 is vague and indefinite in that the metes and bounds of the phrase "..wherein the peptide comprises lys+/arg+." are unclear. It is unclear what is intended by the term "lys+/arg+" as part of the peptide sequence. Does the term specify that the peptide sequence comprise at least one lysine residue and at least one arginine residue anywhere in the sequence? Or does the term specify only one of the two residues, and at the end of the sequence? It would be remedial to amend the claim language to use more conventional terminology to specify exactly what is intended by the term "lys+/arg+".

Claim 10 is vague and indefinite in that the metes and bounds of the phrase "wherein the peptide comprises a clone 20-6 peptide." are unclear. Does the phrase refer to any peptide found within clone 20-6 (e.g. capsid proteins) or does it refer specifically to a peptide sequence that confers resistance to blood inactivation? It would be remedial to amend the claim language to clearly indicate what is intended by the term "a clone 20-6 peptide".

Claim 11 is vague and indefinite in that the metes and bounds of the phrase "..determining peptide-protein interactions using the selected phage." are unclear. Which peptide-protein interactions are intended to be determined? It would be remedial to amend the claim language to clearly indicate which protein-peptide interactions are to be determined as part of the method.

Claim 13 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "the protein" in claim 11, upon which claim 13 is dependent.

Claim 14 is vague and indefinite in that it is a composition claim which comprises methods steps, making it unclear as to whether the invention is a composition or a method. It would be remedial to amend the claim language to clearly indicate that what is being claimed is a composition produced by a particular method.

Claim 14 is also vague and indefinite in that the metes and bounds of the phrases "a peptide specific for drug delivery" and "drug delivery peptide" are unclear. The term "drug delivery peptide" does not appear to be clearly defined in the specification. It would be remedial to amend the claim language to clearly indicate what is intended by the term "drug delivery peptide" and its relationship to the process of claim 1.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Schwartz, can be reached on (703) 308-1133.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GLJ

G. Leffers, Jr.

Patent Examiner

Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER

December 18, 2000